

REMARKS

As an initial matter, Applicants again respectfully submit that claim 11 reads on the species elected in the response filed on January 28, 2008, and thus should not have been withdrawn from consideration in this action. Applicants respectfully request reinstatement of claim 11.

Upon entry of the instant amendment, claims 1, 3, 11-27, 29-31, 33-54 are pending and claims 4, 11-20, 29, 30 and 49-51 are withdrawn in the instant application. Claim 28 is newly cancelled. Claims 1, 33, and 42 are amended. Support for the amendments may be found throughout the specification and claims, and particularly in FIGS. 1 and 3 and paragraphs 75-79 and 82. No new matter has been added, and all of the pending claims are consonant with the election of species made in the response of January 28, 2008.

Claims 1, 3, 21-28, 31, 33-48 and 52-54 stand rejected. Claims 1, 3, 24-25, 27-28 and 52-54 are rejected under 35 USC § 102(e) as being anticipated by U.S. Patent Publication No. 2004/0030391 to Ferree. Claims 21-23 and 26 are rejected under 35 USC § 103(a) as being unpatentable over Ferree in further view of U.S. Patent Publication No. 2003/0204260 to Ferree. Claims 31, 33-44 and 48 are rejected under 35 USC § 103(a) as being unpatentable over Ferree (2004/0030391) and alternately Ferree (2004/0030391) in further view of U.S. Patent Publication No. 2003/0045939 to Casutt. Claims 45-47 are rejected under 35 USC § 103(a) as being unpatentable over Ferree (2004/0030391) in further view of Ferree (2003/0204260) and alternatively Ferree (2004/0030391) in further view of Ferree (2003/0204260) and Casutt.

The rejections, as they may apply to the claims presented herein, are respectfully traversed.

Claim 1 is directed to a two-part prosthetic spinal nucleus device for replacing the nucleus of a spinal disc and being implanted within the annulus. Claim 1 is amended to specify that each shell has an elongate body with a predetermined length between opposite narrow ends and a predetermined width between opposite elongate sides and the smooth outer surfaces have a flat configuration for facing and non-invasively contacting the natural end plate of the adjacent vertebrae. Claim 1 is further amended to specify that inner, arcuate bearing

surfaces of the one-piece bodies of the upper and lower shells each extend substantially entirely across the width of the respective shell bodies to the opposite sides thereof such that the inner, arcuate bearing surfaces have the widthwise size thereof maximized for distributing loading exerted by the adjacent vertebrae across substantially the entire width of the respective shell bodies. None of the relied upon art, either alone or in combination, discloses or suggests a two-part prosthetic spinal nucleus device including upper and lower shells having smooth outer surfaces having flat configurations and inner, arcuate bearing surfaces of the one-piece bodies of the upper and lower shells each extending substantially entirely across the width of the respective shell bodies to the sides thereof such that the inner, arcuate bearing surfaces have the widthwise size thereof maximized for distributing loading exerted by the adjacent vertebrae across substantially the entire width of the respective shell bodies as specified in amended claim 1.

More particularly, Ferree (2004/0030391) discloses a two-piece implant having a central bearing portion configured for disc replacement. The outer facing surfaces of the upper and lower shells of the implant disclosed in FIG. 9A, cited by the Action, are convex. Ferree teaches that the components are convex shaped "to increase the motion across the articulation between the disc spacer components." (See Paragraph 49.) Thus, the outer surfaces do not have flat configurations as required by amended claim 1. The implant of FIG. 9A of Ferree has upper and lower components with convex and concave articulating surfaces therebetween. However, other than providing an elevational and cross-sectional view of the implant of FIG. 9A, Ferree provides no substantial description or teaching of the actual geometry, shape, size and location of the articulating surfaces. Consequently, Ferree fails to disclose or suggest inner, arcuate bearing surfaces extending substantially entirely across the width of the respective shell bodies. The claimed configuration maximizes widthwise size of the inner, arcuate bearing surfaces for more evenly distributing a load exerted by the adjacent vertebrae across substantially the entire width of the respective shell bodies. Such a configuration is advantageous for minimizing the production of wear debris and preventing premature wear or failure of the implant, which can be caused by stress concentrations that may arise in smaller or substantially mismatched

articulation surfaces. Ferree does not consider or address any of these potential problems, and thus does not disclose or suggest the recited bearing surfaces of amended claim 1 that are maximized in their widthwise size across the respective shells. Therefore, Ferree fails to disclose or suggest a two-piece implant with outer surfaces having a flat configuration and inner, arcuate bearing surfaces that extend substantially entirely across the width of the respective shell bodies, as required by claim 1.

For at least the reasons described above, Ferree clearly does not teach, disclose or suggest all of the limitations of independent claim 1. Therefore, Applicants respectfully submit that independent claim 1 is patentable over Ferree. It follows that claims 3, 11, 21-27 and 31, which depend cognately therefrom, are also allowable over Ferree for the reasons mentioned above.

Similarly, independent claim 33 as amended is further believed to be patentable over Ferree in view of Casutt because neither reference discloses or suggests an articulating load bearing implant comprising multiple articulating load bearing members having smooth flat outer bearing surfaces that extend along the entirety of the length and width of each load bearing member or opposing arcuate polyetheretherketone surfaces which extend substantially entirely across the width of each articulating load bearing member. As discussed above, Ferree provides no substantial description or teaching of the actual geometry, shape, size and location of the articulating surfaces. Casutt discloses an intervertebral disc with outer endplates 1,2 with a deformable nucleus therebetween. (Paragraph 29). Although the endplates 1,2 may be made of PEEK, Casutt does not teach or suggest opposing arcuate polyetheretherketone surface that are configured to engage and move against each other. The endplates 1,2 do not contact one another and do not have an arcuate configuration. Thus, the cited art clearly does not teach, disclose or suggest all of the limitations of independent claim 33. Therefore, Applicants respectfully submit that dependent claim 33 is patentable over the combination of Ferree and Casutt. It follows that claims 34-41 which depend cognately therefrom, are believed to be allowable over the combination of Ferree and Casutt for the reasons mentioned above.

Independent Claim 42 as amended is further believed to be patentable over the combination of Ferree and Casutt because neither reference discloses or suggests a nucleus implant device with PEEK inner bearing surfaces of the matched PEEK load bearing members each having an arcuate configuration that extends substantially across the entire width of each of the bearing members including a dome-shaped inner bearing surface of one of the PEEK load bearing members having truncated portions substantially coincident with the opposite sides of the one bearing member such that a diameter of the dome-shaped inner bearing surface is longer than the width of the bearing member to maximize the widthwise size of the dome. As discussed above, Ferree provides no substantial description or teaching of the actual geometry, shape, size and location of the articulating surfaces. Ferree and Casutt clearly do not disclose or suggest a dome-shaped inner bearing surface having truncated portions as claimed in amended claim 42. By substantially maximizing the widthwise size of the dome, the load exerted on the dome is more evenly distributed across the entire width of the bearing member, which advantageously minimizes wear debris and increases implant life. Thus, the cited art clearly does not teach, disclose or suggest all of the limitations of independent claim 42. Therefore, Applicants respectfully submit that dependent claim 42 is patentable over the combination of Ferree and Casutt. It follows that claims 43-48 which depend cognately therefrom, are believed to be allowable over the combination of Ferree and Casutt for the reasons mentioned above.

As discussed above, the relied upon art does not disclose or suggest all of the limitations of independent claims 1, 33, or 42. Therefore, claims 1, 33 and 42, as well as claims 3, 21-27, 31, 34-41, 43-48 and 52-54 which depend cognately therefrom, are believed to be allowable over the relied upon art. Based on the foregoing, reconsideration and allowance of claims 1, 3, 21-27, 31, 33-48 and 52-54 are respectfully requested.

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The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,
FITCH, EVEN, TABIN & FLANNERY

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